

AMENDMENTS

Applicant requests that the Examiner enter the following amendments:

IN THE CLAIMS:

1. (Currently amended) A method for detecting overexpression of a human RNA species in blood plasma or serum from a human, the method comprising the steps of:
 - a) extracting total extracellular RNA from blood plasma or serum from a human;
 - b) amplifying or signal amplifying quantitatively or qualitatively a portion of the extracted RNA or cDNA therefrom to produce an amplified product or signal, using primers or probes specific for a human RNA species or cDNA therefrom; and
 - c) detecting quantitatively or qualitatively the amplified product or signal and comparing the detected amplified product or signal to a reference amplified product or signal of said human RNA species or cDNA extracted from plasma or serum from a human group or population without disease,

wherein [a] the human RNA species extracted from human blood plasma or serum is determined to be overexpressed when said RNA species or cDNA therefrom is detected in an amount or concentration greater than the reference ~~amplified product or signal~~ amount or concentration of said RNA species or cDNA therefrom extracted from blood plasma or serum from a human group or population without ~~said~~ disease.

2. (Currently Amended) [A] The method according to claim 1, wherein the human RNA species is a tumor-associated extracellular RNA species and overexpression of ~~a said~~ tumor-associated extracellular RNA species in the human blood plasma or serum ~~indicates that the disease is associated with the presence of a neoplastic disease that is~~ characterized by said RNA species.

3. (Withdrawn) The method of claim 1, wherein the amplified product is produced from a non-tumor related RNA or cDNA produced therefrom.
4. (Currently amended) The method of claim 1, wherein the amplified product in step (b) is produced from a tumor related RNA or cDNA produced therefrom.
5. (Currently amended) A method for detecting overexpression of a human RNA species in a non-cellular fraction of blood from a human, the method comprising the steps of:
 - a) extracting total extracellular RNA from a non-cellular fraction of blood from a human;
 - b) amplifying or signal amplifying quantitatively or qualitatively a portion of the extracted RNA or cDNA therefrom to produce an amplified product or signal, using primers or probes specific for a human RNA species or cDNA therefrom; and
 - c) detecting quantitatively or qualitatively the amplified product or signal and comparing the detected amplified product or signal to a reference amplified product or signal of said RNA or cDNA extracted from a non-cellular fraction fractions of blood from a human group or population without a disease,

wherein [a] the human RNA species extracted from a non-cellular fraction of human blood is determined to be overexpressed when said RNA species, or cDNA therefrom, is detected in an amount or concentration greater than the reference ~~amplified product or signal~~ amount or concentration of said RNA species or cDNA therefrom extracted from non-cellular fractions of blood from a human group or population without ~~said~~ disease.
6. (Currently Amended) [A] The method according to claim 5, wherein the human RNA species is a tumor-associated extracellular RNA species and overexpression of said

~~disease is a neoplastic disease when a tumor-associated RNA species in the non-cellular fraction of human blood plasma or serum is overexpressed associated with the presence of a neoplastic disease that is characterized by said RNA species.~~

7. (Withdrawn) The method of claim 5, wherein the amplified product is produced from a non-tumor related RNA or cDNA produced therefrom.
8. (Currently amended) The method of claim 5, wherein the amplified product in step (b) is produced from a tumor related RNA or cDNA produced therefrom.
9. (Currently amended) A method for comparing an amount or concentration of a human RNA species present in plasma or serum from a human to a reference range RNA amount or concentration for said RNA species present in plasma or serum from a group or population of humans without cancer, the method comprising the steps of extracting total extracellular RNA from plasma or serum from a human, a portion of which comprises a human RNA species, determining an amount or concentration of said human RNA species in the extracted portion of human blood plasma or serum, and comparing the amount or concentration of said human RNA species from plasma or serum of said human to the reference range RNA amount or concentration determined from plasma or serum from a human group or population without cancer.
10. (Withdrawn) The method of claim 9, wherein the defined group or population comprises healthy humans.
11. (Withdrawn) The method of claim 9, wherein the defined group or population comprises healthy animals.
12. (Previously presented) The method of claim 9, wherein the human has cancer.
13. (Cancelled)

14. (Previously presented) The method of claim 9, wherein the human has not been diagnosed with cancer.
15. (Cancelled)
16. (Cancelled)
17. (Previously presented) The method of claim 9, wherein the group or population comprises humans of a specific gender or age group.
18. (Previously presented) The method of claim 9, wherein the group or population comprises humans who smoke.
19. (Withdrawn) The method of claim 9, wherein the defined group or population comprises humans with a family or genetic history of cancer or cancer risk.
20. (Currently amended) A method for comparing an amount or concentration of an extracellular human RNA species present in non-cellular fractions of blood from a human to a reference range RNA amount or concentration for said RNA species present in non-cellular fractions of blood from a group or population of humans without cancer, the method comprising the steps of extracting total extracellular RNA from a non-cellular fraction of blood from a human, a portion of which comprises a human RNA species, determining an amount or concentration of said human RNA species in the extracted portion of a non-cellular fraction of blood from the human, and comparing the amount or concentration of said human RNA species from a non-cellular fraction of blood of said human to the reference range RNA amount or concentration for said human RNA species determined from non-cellular fractions of blood from a human group or population without cancer.

21. (Withdrawn) The method of claim 20, wherein the defined group or population comprises healthy humans.
22. (Withdrawn) The method of claim 20, wherein the defined group or population comprises healthy animals.
23. (Previously presented) The method of claim 20, wherein the human has cancer.
24. (Cancelled)
25. (Previously presented) The method of claim 20, wherein the human has not been diagnosed with cancer.
26. (Cancelled)
27. (Cancelled)
28. (Previously presented) The method of claim 20, wherein the group or population comprises humans of a specific sex or age group.
29. (Previously presented) The method of claim 20, wherein the group or population comprises humans who smoke.
30. (Withdrawn) The method of claim 20, wherein the defined group or population comprises humans with a family or genetic history of cancer or cancer risk.

Claims 31-32. (Cancelled)

33. (Withdrawn) A method of evaluating a human or animal for a disease comprising the step of assaying quantitatively blood plasma or serum from the human or animal to determine an amount or concentration of a non-tumor related RNA.
34. (Withdrawn) A method of evaluating a human or animal for a disease comprising the step of assaying quantitatively non-cellular fraction of a bodily fluid from the human or animal to determine an amount or concentration of a non-tumor related RNA.

Claims 35-44. (Cancelled)

45. (Currently amended) [A] ~~The method of~~according to claim 9, wherein the human is ~~determined to have~~ has a cancer and wherein the RNA species is a tumor-associated RNA.
46. (Currently amended) [A] ~~The method of~~according to claim 20, wherein the human is ~~determined to have~~ has a cancer and wherein the RNA species is a tumor-associated RNA.

Claims 47-48 (Cancelled)

49. (Withdrawn) The method of claim 33, wherein the disease is cancer or premalignancy.
50. (Withdrawn) The method of claim 34, wherein the disease is cancer or premalignancy.